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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,687	12/05/2003	E. Gerald Slautterback	3877	9083

7590

12/03/2004

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EXAMINER
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ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/728,687

Applicant(s)

SLAUTTERBACK ET AL.

Examiner

Shumaya B. Ali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: detailed action.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

***Claim 1-4, 9-12, and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Hicks US Patent 5,372,576 in view of Sun et al. US Patent 6,600,085***

1. **As to claim 1, Hicks** discloses an AFO/contracture foot splint (see fig.1 reference object 10) device for alleviating and correcting foot deformities, treating foot drop, preventing decubitus ulceration of the calcaneus (heel bone), by maintaining the foot in a fixed, stable, yet comfortable position following surgery or other medical procedure performed on the foot, said device comprising: a leg engaging portion (see fig.1 reference object 12); a foot supporting portion (fig.1 reference object 14); a heel portion (see fig.1 reference object 16) having a heel well (see fig.1 reference object 26a); a toe extension portion (see fig.2 reference object 30); a disposable liner (see fig.2 reference object 30); wherein the heel portion prevents contact between an upper surface of the heel portion of the device and the heel of the wearer thereby eliminating chafing, or abrasive contact, or decubitus ulceration, or pain-inducing pressure (see col.1 lines 14-23, 44-48). **As to claim 1, Hicks** however does not disclose the disposable liner is comprised of a fluid permeable layer; an absorbent layer and moisture proof layer.

2. **AS to claim 1, Sun et al.** teaches a disposable therapeutic absorbent article (i.e. sanitary protection products, and bandages) comprising a fluid permeable layer (see fig.4, reference objects 56), an absorbent layer (see fig.3 reference objects 24 a-c) and moisture proof layer (top layer) (see fig.3 reference object 32).

3. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the liner of Hicks in view of Sun et al. in order to provide the liners with both cushioning and therapeutic values for the purposes of eliminating the discomfort from wet liners through the selection of a

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material that contains a permeable, protective layer next to the skin, an absorbent antimicrobial core layer that pulls moisture away from the skin, and a moisture proof backing to contain fluids.

4. **As to claims 2 and 10 Hicks does not disclose** the disposable liner further comprises an antimicrobial additive.

5. **As to claims 2 and 10, Sun et al.** teaches a disposable therapeutic absorbent article comprising an antimicrobial additive (see col.2, lines 64-65).

6. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the liner of Hicks in view of Sun et al. in order to provide the liner with antimicrobial additive for the purposes of preventing microbial agent or increasing antibiotic characteristics of the liner.

7. **As to claims 3 and 11, Hicks does not disclose** the antimicrobial additive is triclosan

8. **As to claims 3 and 11, Sun et al.** additionally teaches the antimicrobial additive is triclosan (see col.2 lines 64-65).

9. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the liner of Hicks in view of Sun et al. in order to manufacture the liner with triclosan antimicrobial for the purposes of permanently disabling an ENR molecule, therefore, adding a powerful antibiotic characteristic to the liner at a low concentration of triclosan.

10. **As to claim 9, Hicks does not disclose** absorbent layer is a multi-strata layer of a relatively high level of a superabsorbent in a stratum, and a high level of a cellulosic wood fiber matrix or pulp in an adjacent stratum.

11. **As to claim 9, Sun et al.** teaches a therapeutic absorbent article comprising a superabsorbent multi-strata absorbent layer (see col.7 lines 41-63), whereas the absorbent core made from various materials including cellulosic wood fiber matrix or pulp (see col.1 lines 57-67).

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12. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the liner of Hicks in view of Sun et al. in order to provide the liner with breathable fibrous layer for the purposes of providing a comfortable padding for the foot and leg of a patient.

13. **As to claim 17, Hicks does not disclose** a liner for an AFO/contracture foot splint device, wherein said liner is a disposable liner that is sufficiently soft and flexible so as to comfortably conform to body surface and provide for substantially a close fit to prevent leakage, said liner comprising: a fluid permeable layer; an absorbent layer. The function of the absorbent layer is to absorb and retain body fluids entering the disposable liner through the fluid permeable layer; a moisture proof layer which is a liquid impervious back sheet disposed on the outer surface of the liner, and is designed to prevent the leakage of fluids; and wherein the moisture proof layer is breathable and has a high MVTR.

14. **As to claim 17, Sun et al. teaches** a disposable absorbent article or bandage comprising: a fluid permeable layer (see fig.4 reference object 56); an absorbent layer (see fig.3, reference objects 24a-c). The function of the absorbent layer is to absorb and retain body fluids entering the disposable liner through the fluid permeable layer (see fig.4 reference object 56); a moisture proof layer (see fig.3 reference object 32) which is a liquid impervious back sheet disposed on the outer surface of the liner, and is designed to prevent the leakage of fluids (see col.4 lines 27-31); and wherein the moisture proof layer is breathable and has a high MVTR (see col.8 lines 10-46).

15. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the liner of Hicks in view of Sun et al. in order to provide the liners with three claimed layers for the purposes of eliminating the discomfort from wet liners through the selection of a material that contains a permeable, protective layer next to the skin, an absorbent antimicrobial core layer that pulls moisture away from the skin, and a moisture proof backing to contain fluids.

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16. As to claims 4 and 12, Hicks discloses the leg portion; the heel portion, the foot-supporting portion, and the toe portion are portions comprising a shell (see fig.1)

***Claims 5-8,13-16,18-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Hicks US Patent 5,372,576 and Sun et al. US Patent 6,600,085 and in view of Lamont US Patent 5,762,622***

17. As to claims 5 and 13 Hicks discloses the disposable liner is a single piece having a outer pocket at the leg portion (see fig.5 reference object 34 col.3 lines 11-15), however, **as to claims 5,13, and 24, Hicks does not disclose** pocket at the toe extension portion to accept and secure the liner to the shell.

18. As to claims 5,13, and 24, Lamont teaches the bottom side of an insole liner of a diabetic boot comprising a pair of pockets for receiving the heel and toe of insole (see fig.6 reference objects 72 and 74). Lamont's insole toe pocket at the toe extension portion is capable of accepting and securing the liner to the shell (see fig.12 reference objects 12A and 84)

19. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the liner of Hicks and absorbent article of Sun et al. in view of Lamont in order to provide the liner with a toe extension portion for the purposes of accepting and securing the liner to the shell.

20. As to claim 18, Hicks discloses the liner is one piece comprising a foot region (see fig.2 reference object 30a) a leg end (see fig.2 reference object 30 near leg end); a leg region (see fig.2 reference object 30b); a heel region (see fig.2 area of the reference object 32); wherein the foot region has winged extension (flaps) terminated with fastening elements (see fig.2 reference objects 50a, 52), said winged extension being foldable over the foot and fastened (see fig.5); thereby securing the foot region; wherein the leg end of the liner has tabular extension terminated with re-closable fastening elements (see fig.2 reference objects 46 and 48), said tabular extensions being foldable around the calf of the leg and fastened, thereby securing the leg region of the disposable liner to the leg (see col.3 lines 33-37); wherein

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said heel region of the liner has an opening (see fig.2 reference object 32), which enables a portion of the wearer's heel to project through the heel region into heel "well" (see fig.1 reference object 26a) of a splint; and wherein the liner on either side of the heel opening is gathered and stitched or welded to draw the foot of the liner upward to the correct angle and eliminate bulkiness and pressure points (see col.4 lines 16-20).

**As to claim 18, Hicks** however, does not disclose the liner having a toe end.

21. **As to claim 18, Lamont** teaches the bottom side of an insole liner of a diabetic boot with a toe end (see fig.5 reference object 64).

22. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the liner of Hicks and absorbent article of Sun et al. in view of Lamont in order to provide the liner with a toe end for the purposes of laying the toe of a patient on a cushioning means.

23. **As to claim 19, Hicks** does not disclose the absorbent layer is comprised of a cellulosic wood fiber matrix or pulp, which pulp is capable of absorbing large quantities of fluid.

24. **As to claim 19, Sun et al.** teaches an absorbent core of a bandage comprising a cellulosic wood fiber matrix of pulp (see col.1 lines 57-67, which pulp is capable of absorbing large quantities of fluid (see col.7 lines 41-42, col.8 lines 1-9)

25. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the liner of Hicks in view of Sun et al. in order to provide the absorbent layer of the liner with breathable fibrous matrix for the purposes of absorbing large quantities of fluid.

26. **As to claim 20, Hicks** does not disclose the absorbent layer is further comprised of a superabsorbent amongst the fiber matrix.

27. **As to claim 20,** applicant discloses the superabsorbent layer can contain complex forming agents such as polymeric olefins and polyacids. **As to claim 20, Sun et al.** teaches the absorbent layer is further

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comprised of a superabsorbent (with polyolefins and polypropylene) amongst the fiber matrix (see col.3 lines 22-32, col.7 lines 41-67, col.8 lines 1-9)

28. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the liner of Hicks in view of Sun et al. in order to provide the absorbent layer with superabsorbent characteristics for the purposes of absorbing large quantities of fluid.

29. As to claim 21, Hicks does not disclose the absorbent layer is further comprised of complex forming agents, which are cationic and anionic binder for the superabsorbent.

30. As to claim 21, Sun et al. teaches the absorbent layer is further comprised of complex forming agents (with polyolefins and polypropylene), which are cationic and anionic binders for the superabsorbent (see col.3 lines 6-32).

31. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the liner of Hicks in view of Sun et al. in order to provide the superabsorbent layer with cationic and anionic binder for the purposes of holding the superabsorbent material within the material.

32. As to claim 22, Hicks does not disclose the disposable liner further comprises an antimicrobial additive.

33. As to claim 22, Sun et al. teaches a disposable therapeutic absorbent article comprising an antimicrobial additive (see co.2, lines 64-65).

34. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the liner of Hicks in view of Sun et al. in order to provide the liner with antimicrobial additive for the purposes of preventing microbial agent or increasing antibiotic characteristics of the liner.

35. As to claim 23, Hicks does not disclose the antimicrobial additive is triclosan



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36. **As to claim 23, Sun et al.** additionally teaches the antimicrobial additive is triclosan (see col.2 lines 64-65).

37. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the liner of Hicks in view of Sun et al. in order to manufacture the liner with triclosan antimicrobial for the purposes of permanently disabling an ENR molecule, therefore, adding a powerful antibiotic characteristic to the liner at a low concentration of triclosan.

38. **As to claims 6 and 14, Hicks** discloses the liner has hook and loop straps on the moisture proof layer to secure said disposable liner to the leg (see fig.5 reference objects 46 and 48) and the foot of the user (see fig.5 reference object 62 col.3 lines 33-37).

39. **AS to claims 7 and 15, Hicks** discloses the liner has a heel area that is cut out (see fig.2 reference object 32) forming a heel opening (see col.3 lines 21-25), wherein the heel opening is gathered and stitched or welded to draw the foot of the liner upward to the correct angle and eliminate bulkiness and pressure points.

40. **As to claims 8 and 16, Hicks** discloses the splint is further provided with additional adjustable straps attached to flaps, which overlap the disposable liner (see fig.2 reference objects 50 a-a col.3 lines 38-48).

41. **As to claim 25, Hicks** discloses the leg end of the liner has a leg pocket that fits onto a leg engaging portion of a splint's shell (see fig.5 reference object 34 col.3 lines 11-15).

### ***Conclusion***

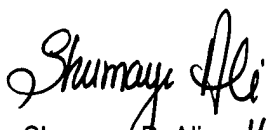
42. The prior art of record and not relied upon is considered pertinent to applicant's disclosure: US 5,885,236 A, US 6,090,059 A, and US 6,432,073 B1 disclose AFO device with comfortable liner.

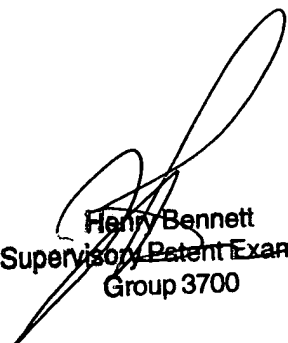
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43. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-F 8:30 am-4:30 pm.

44. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-6088.

45. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Shumaya B. Ali  
Examiner  
Art Unit 3743  
11/29/04

  
Henry Bennett  
Supervisory Patent Examiner  
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